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JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET ATLANTA, GA 30309			EXAMINER HENRY, MICHAEL C	
			ART UNIT 1623	PAPER NUMBER

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/635,928

Applicant(s)

VENKATARAMAN, BALAJI

Examiner

Michael C. Henry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 07/23/04.

The amendment filed 07/23/04 affects the application, 10/635,928 as follows:

1. Claims 1,11,15,18,19,23 and 24 have been amended. Claim 6 has been canceled.

New claims 25-33 have been added. This leaves claims 1-5 and 7-33.

2. Applicant responds to the rejections under 35 USC 112, 102 and 103 by amending claims 1,11,15,18,19,23 and 24, canceling claim 6 and adding new claims 25-33.

The responsive to applicants' arguments is contained herein below.

Claims 1-5 and 7-33 are pending in application

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,3,10,13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Paradissis et al. (US 5,494,678).

In claim 1, applicants claim "A composition for treating a condition associated with a hormonal change comprising calcium, vitamin D, folic acid in an amount between about 0.8 mg and 5 mg, vitamin B12 and vitamin B6." Paradissis et al. disclose applicant's composition for treating a condition associated with a hormonal change (pregnancy) comprising calcium, vitamin D, 1 mg of folic acid, vitamin B12 and vitamin B6 (see col. 10, Example, lines 25-56). It should be noted that the intended use of the composition does not add to patentability of the composition

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claimed. The examiner gives very little weight to this functional language. In claim 2, applicant claims “The composition of claim 1, wherein the calcium is in an amount less than 800 mg. Paradissis et al. disclose applicant’s composition of claim 1, wherein the calcium is in an amount less than 800 mg (i.e., 250 mg) (see col. 10, Example, lines 25-56). In claim 3, applicant claims “The composition of claim 1, wherein the calcium is in an amount between about 200 mg and 800 mg. Paradissis et al. disclose applicant’s composition of claim 1, wherein the calcium is in an amount between about 200 mg and 800 mg (i.e. 250 mg) (see col. 10, Example, lines 25-56). In claim 10, applicant claims “The composition of claim 1, wherein the vitamin B6 is in an amount between about 10 mg and 100 mg. Paradissis et al. disclose applicant’s composition of claim 1, wherein the vitamin B6 is in an amount between about 10 mg and 100 mg (i.e. 16 mg) (see col. 10, Example, lines 25-56). In claim 13, applicant claims “The composition of claim 1 further comprising vitamin C in an amount less than about 200 mg.” Paradissis et al. disclose applicant’s composition of claim 1 further comprising vitamin C in an amount less than about 200 mg (i.e. 80 mg) (see col. 10, Example, lines 25-56).” In claim 14, applicant claims “The composition of claim 1 further comprising iron in an amount of between about 20 mg and 75 mg.” Paradissis et al. disclose applicant’s composition of claim 1 further comprising iron in an amount of between about 20 mg and 75 mg.” (i.e. 65 mg) (see col. 10, Example, lines 25-56).”

Claims 1,2,3,10, 11, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Rowland (US 5,405,613).

In claim 1, applicants claim “A composition for treating a condition associated with a hormonal change comprising calcium, vitamin D, folic acid in an amount between about 0.8 mg and 5 mg, vitamin B12 and vitamin B6.” Rowland discloses applicant’s composition comprising

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calcium (40 to 200 mg), vitamin D (50-400 I.U.), 0.002 to 1mg of folic acid, vitamin B12 (3 to 1,000 mcg) and vitamin B6 (3 to 100 mg) (see col. 10, table 1, lines 8-33). It should be noted that the intended use of the composition does not add to patentability of the composition claimed. The examiner gives very little weight to this functional language. Claims 2,3,10, 11, 13 and 14 which are drawn to specific amounts of the components of the composition of claim 1, are also anticipated by Rowland, since Rowland composition also contain the same components in same amounts (see col. 10, table 1, lines 8-33).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowland (US 5,405,613).

In claim 15, applicant claims "A method of treating a condition associated with a hormonal change in an individual comprising administering to the individual an effective amount of a vitamin composition comprising calcium, vitamin D, folic acid in an amount between about 0.8 mg and 5 mg, vitamin B12 and vitamin B6." Claims 16-22 which are further limitations of claim 15, are drawn to the use of said composition comprising specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and, specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3) and treating hormonal change caused by specific conditions including menopause.

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Rowland discloses a method to restore energy balance or intensity, or to support or enhance a bioenergetic field in a mammal comprising administering to a mammal an effective amount of shilajit or extracts thereof in a vitamin and/or mineral preparation (see col. 2, lines 62-67). Rowland discloses that the ingredients of an exemplary commonly used vitamin and/or mineral preparation (which includes a composition comprising calcium, vitamin D, folic acid in an amount between about 0.002 mg to 1 mg), vitamin B12 and vitamin B6, are set forth in Table 1 (see col. 4, lines 14-30 and col. 10, table 1, lines 8-33). Furthermore, Rowland discloses that the composition is useful in treating conditions which include menopause and premenstrual syndrome (see col. 5, lines 22-40). In addition, Rowland discloses that the concentration of the vitamin and/or mineral components used in the composition will depend on individual needs and on the desired effect (see col. 4, lines 14-30).

The difference between applicant's claimed method and the Method of Rowland is that Rowland does not specifically exemplify the use of the said vitamin composition to treat a condition associated with a hormonal change, per se, and does not disclose the use of any specific vitamin B12 (such as hydroxocobalamin) and vitamin D (such as D3). However, Rowland discloses that the composition is useful in treating conditions the menopause which is a condition associated with a hormonal change (see col. 5, lines 22-40) and that vitamin B12 and vitamin D can be used (col. 10, table 1, lines 8-33).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to use the method suggested by Rowland to treat a condition associated with a hormonal change (such as menopause) and to use any amount or quantity of the components used by Rowland including any type of vitamin D and B12 (such as vitamin D3 and

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hydroxocobalamin), since Rowland discloses that vitamin D and vitamin B12 can be used in general, and the amount or quantity of the components used in the composition depends on factors such as the severity of the condition and the mass or age of individual being treated.

One having ordinary skill in the art would have been motivated to use the method suggested by Rowland to treat a condition associated with a hormonal change (such as menopause) and to use any amount or quantity of the components used by Rowland including any type of vitamin D and B12 (such as vitamin D3 and hydroxocobalamin), since Rowland discloses that vitamin D and vitamin B12 can be used in general, and the amount or quantity of the components used in the composition depends on factors such as the severity of the condition and the mass or age of individual being treated.

Claims 1-5,7-14,23-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (US 6,040,333).

In claim 1, applicant claims "A composition for treating a condition associated with a hormonal change comprising calcium, vitamin D, folic acid in an amount between about 0.8 mg and 5 mg, vitamin B12 and vitamin B6." Claims 2-5, 7-14, 31 which are further limitations of claim 1, are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and, specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3).

Jackson discloses a composition for treating a condition associated with a hormonal change (menopause) comprising calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 (see col. 11, table 1, lines 17-36).

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The difference between applicant's claimed composition and the composition of Jackson is amount or quantity of the components used in the composition and the specific type of vitamin D and B12 (hydroxocobalamin). However, Jackson discloses that vitamin D and vitamin B12 can be used, and the amount or quantity of the components used in the composition depends on factor like the severity of the condition and the mass or age of individual being treated.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to prepare Jackson's composition and to use any amount or quantity of the components used by Jackson including any type of vitamin D and B12 (such as vitamin D3 and hydroxocobalamin), since Jackson discloses that vitamin D and vitamin B12 can be used in general, and the amount or quantity of the components used in the composition depends on factors such as the severity of the condition and the mass or age of individual being treated.

One having ordinary skill in the art would have been motivated to prepare Jackson's composition and to use any amount or quantity of the components used by Jackson including any type of vitamin D and B12 (such as vitamin D3 and hydroxocobalamin), since Jackson discloses that vitamin D and vitamin B12 can be used in general, and the amount or quantity of the components used in the composition depends on factors such as the severity of the condition and the mass or age of individual being treated.

In claim 15, applicant claims "A method of treating a condition associated with a hormonal change in an individual comprising administering to the individual an effective amount of a vitamin composition comprising calcium, vitamin D, folic acid in an amount between about 0.8 mg and 5 mg, vitamin B12 and vitamin B6." Claims 16-19 which are further limitations of claim 15, are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and

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vitamin B6 and, specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3). Dependent claims 20-22 are drawn to the method of claim 15 wherein the composition further comprises specific amounts of vitamin C and iron, and the treating of hormonal change caused by specific conditions including menopause.

Jackson discloses a method of treating a condition associated with a hormonal change (menopause) in an individual comprising administering to the individual an effective amount of a vitamin composition comprising calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 (see col. 11, table 1, line 17 to col. 12, line 20 and, example 1, col. 13, lines 43-64).

The difference between applicant's claimed method and the method of Jackson is amount or quantity of the components used in the composition and the specific type of vitamin D and B12 (hydroxocobalamin). However, Jackson discloses that vitamin D and vitamin B12 can be used, and the amount or quantity of the components used in the composition depends on factor like the severity of the condition and the mass or age of individual being treated.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to use Jackson's method to treat a condition associated with a hormonal change and to use any amount or quantity of the components used by Jackson including any type of vitamin D and B12 (such as vitamin D3 and hydroxocobalamin), since Jackson discloses that vitamin D and vitamin B12 can be used in general, and the amount or quantity of the components used in the composition depends on factors such as the severity of the condition and the mass or age of individual being treated.

One having ordinary skill in the art would have been motivated to use Jackson's method to treat a condition associated with a hormonal change and to use any amount or quantity of the

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components used by Jackson including any type of vitamin D and B12 (such as vitamin D3 and hydroxocobalamin), since Jackson discloses that vitamin D and vitamin B12 can be used in general, and the amount or quantity of the components used in the composition depends on factors such as the severity of the condition and the mass or age of individual being treated.

In claim 23, applicant claims “A composition for treating a condition associated with a hormonal change comprising calcium, vitamin D, folic acid in an amount between about 0.8mg and 5mg, hydroxocobalamin and vitamin B6.

Jackson discloses a composition for treating a condition associated with a hormonal change (menopause) comprising calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 (see col. 11, table 1, lines 17-36).

The difference between applicant’s claimed composition and the composition of Jackson is amount or quantity of the components used in the composition and the specific type of vitamin B12 (hydroxocobalamin). However, Jackson discloses that vitamin B12 can be used, and the amount or quantity of the components used in the composition depends on factor like the severity of the condition and the mass or age of individual being treated.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to prepare Jackson’s composition and to use any amount or quantity of the components used by Jackson including any type of vitamin B12 (such as hydroxocobalamin), since Jackson discloses that vitamin B12 can be used in general, and the amount or quantity of the components used in the composition depends on factors such as the severity of the condition and the mass or age of individual being treated.

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One having ordinary skill in the art would have been motivated to prepare Jackson's composition and to use any amount or quantity of the components used by Jackson including any type of vitamin B12 (such as hydroxocobalamin), since Jackson discloses that vitamin B12 can be used in general, and the amount or quantity of the components used in the composition depends on factors such as the severity of the condition and the mass or age of individual being treated.

In claim 24, applicant claims "A method of treating a condition associated with a hormonal change in an individual comprising administering to the individual an effective amount of a vitamin composition comprising calcium, vitamin D, folic acid in an amount between about 0.8mg and 5mg, hydroxocobalamin and vitamin B6. Claim 32 is drawn to the method of claim 24 wherein the hydroxocobalamin is in an amount of about 500 mcg.

Jackson discloses a method of treating a condition associated with a hormonal change (menopause) in an individual comprising administering to the individual an effective amount of a vitamin composition comprising calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 (see col. 11, table 1, line 17 to col. 12, line 20 and, example 1, col. 13, lines 43-64).

The difference between applicant's claimed method and the method of Jackson is amount or quantity of the components used in the composition and the specific type of vitamin B12 (hydroxocobalamin). However, Jackson discloses that vitamin B12 can be used, and the amount or quantity of the components used in the composition depends on factor like the severity of the condition and the mass or age of individual being treated.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to use Jackson's method to treat a condition associated with a hormonal

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change and to use any amount or quantity of the components used by Jackson including any type of vitamin B12 (such as hydroxocobalamin), since Jackson discloses that vitamin B12 can be used in general, and the amount or quantity of the components used in the composition depends on factors such as the severity of the condition and the mass or age of individual being treated.

One having ordinary skill in the art would have been motivated to use Jackson's method to treat a condition associated with a hormonal change and to use any amount or quantity of the components used by Jackson including any type of vitamin D and B12 (such as vitamin D3 and hydroxocobalamin), since Jackson discloses that vitamin D and vitamin B12 can be used in general, and the amount or quantity of the components used in the composition depends on factors such as the severity of the condition and the mass or age of individual being treated.

In claim 25, applicant claims "A composition for treating a condition associated with a hormonal change comprising calcium, vitamin D, folic acid, hydroxocobalamin in an amount between about 300 mcg and 2000 mcg, and vitamin B6. Dependent claims 26-29 are drawn to a said composition comprising to specific amounts of hydroxocobalamin and folic acid

Jackson discloses a composition for treating a condition associated with a hormonal change (menopause) comprising calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 (see col. 11, table 1, lines 17-36).

The difference between applicant's claimed composition and the composition of Jackson is amount or quantity of the components used in the composition and the specific type of vitamin B12 (hydroxocobalamin). However, Jackson discloses that vitamin B12 can be used, and the amount or quantity of the components used in the composition depends on factor like the severity of the condition and the mass or age of individual being treated.

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It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to prepare Jackson's composition and to use any amount or quantity of the components used by Jackson including any type of vitamin B12 (such as hydroxocobalamin), since Jackson discloses that vitamin B12 can be used in general, and the amount or quantity of the components used in the composition depends on factors such as the severity of the condition and the mass or age of individual being treated.

One having ordinary skill in the art would have been motivated to prepare Jackson's composition and to use any amount or quantity of the components used by Jackson including any type of vitamin B12 (such as hydroxocobalamin), since Jackson discloses that vitamin B12 can be used in general, and the amount or quantity of the components used in the composition depends on factors such as the severity of the condition and the mass or age of individual being treated.

In claim 30, applicant claims "A method of treating a condition associated with a hormonal change in an individual comprising administering to the individual an effective amount of a vitamin composition comprising calcium, vitamin D, folic acid, hydroxocobalamin in an amount of about 300 mcg and 1200 mcg, and vitamin B6. Claim 33 is drawn to the method of claim 30 wherein the hydroxocobalamin is in an amount of about 500 mcg.

Jackson discloses a method of treating a condition associated with a hormonal change (menopause) in an individual comprising administering to the individual an effective amount of a vitamin composition comprising calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 (see col. 11, table 1, line 17 to col. 12, line 20 and, example 1, col. 13, lines 43-64).

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The difference between applicant's claimed method and the method of Jackson is amount or quantity of the components used in the composition and the specific type of vitamin B12 (hydroxocobalamin). However, Jackson discloses that vitamin B12 can be used, and the amount or quantity of the components used in the composition depends on factor like the severity of the condition and the mass or age of individual being treated.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to use Jackson's method to treat a condition associated with a hormonal change and to use any amount or quantity of the components used by Jackson including any type of vitamin B12 (such as hydroxocobalamin), since Jackson discloses that vitamin B12 can be used in general, and the amount or quantity of the components used in the composition depends on factors such as the severity of the condition and the mass or age of individual being treated.

One having ordinary skill in the art would have been motivated to use Jackson's method to treat a condition associated with a hormonal change and to use any amount or quantity of the components used by Jackson including any type of vitamin D and B12 (such as vitamin D3 and hydroxocobalamin), since Jackson discloses that vitamin D and vitamin B12 can be used in general, and the amount or quantity of the components used in the composition depends on factors such as the severity of the condition and the mass or age of individual being treated.

Response to Amendment

Applicant's arguments with respect to claims 1-5 and 7-24 have been considered but are moot in view of the new ground(s) of rejection.

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The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

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MCH

October 12, 2004.

all Paul
JULI FESELEV
PRIMARY EXAMINER
GROUP 1800